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Ocular Gene Therapy Showed Fewer Injections Needed, Increased Visual Gain

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Subretinal delivery of an ocular gene therapy drug was well tolerated, required fewer injections of anti-VEGF, and improved visual acuity in a phase 1 randomized clinical trial in patients with wet AMD, reported Thomas W. Chalberg, PhD, at Angiogenesis, Exudation, and Degeneration 2014.¹

One hundred microliters of AVA-101 [Ocular BioFactory, Avalanche Biotechnologies] was injected subretinally in patients. Anti-VEGF protein levels increased over 6 to 8 weeks, during which 2 injections of ranibizumab were given. After 8 weeks, ranibizumab was given to the treatment group on a prn basis as rescue therapy.

Patients were tracked for 12 months after injection at monthly visits. The control group, which did not receive an injection of AVA-101, required a mean 3 injections of ranibizumab during the 12-month period. The treatment group required a mean 0.3 ranibizumab injections over the same period.

Patients received ranibizumab injections if fluid appeared on OCT or fluorescein angiography, or if there was vision loss attributable to increased area of choroidal neovascularization.

Patients in the study had experience with anti-VEGF treatment, averaging 18 intravitreal anti-VEGF treatments prior to study enrollment.

"Because these patients are coming heavily pretreated, we didn't necessarily expect them to gain additional vision," Dr. Chalberg said. "But treated patients actually gained between 9 and 12 letters over 12 months."

Dr. Chalberg reported no drug-related adverse events, retinal tears, or retinal detachments. Procedure-related adverse events were minor and self-resolving.

"Ocular gene therapy might be a long-term viable option for patients with wet AMD," Dr. Chalberg said.

AVA-101 is a strand of therapeutic DNA packaged inside an adeno-associated virus (AAV) vector. When injected subretinally, AVA-101 up-regulates the body's production of anti-VEGF. Subretinal injection appeared to be safe and was well-tolerated, Dr. Chalberg reported, and allowed AVA-101 injections to better stimulate anti-VEGF production than if delivered intravitreally.

Dr. Chalberg said that an ongoing phase 2A study currently has 40 patients enrolled.

1. Chalberg TW. Anti-VEGF gene therapy: early clinical results using the ocular biofactory in wet AMD. Paper presented at: Angiogenesis, Exudation, and Degeneration 2014; February 8, 2014; Miami, FL.

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Contact Info

Bryn Mawr Communications LLC
1008 Upper Gulph Road, Suite 200
Wayne, PA 19087

Phone: 484-581-1800
Fax: 484-581-1818

Karen Roman
Editor-in-Chief
484-581-1827
kroman@bmctoday.com

Alan B. Guralnick
Publisher
484-581-1832
aguralnick@bmctoday.com

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